

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE**

**IN RE: VALSARTAN, LOSARTAN,
AND IRBESARTAN PRODUCTS
LIABILITY LITIGATION**

This Document Relates to All Actions

MDL No. 2875

Honorable Robert B. Kugler,
District Court Judge

Honorable Joel Schneider,
Magistrate Judge

**MANUFACTURER DEFENDANTS' OMNIBUS REPLY BRIEF IN
FURTHER SUPPORT OF MOTION TO QUASH AND FOR PROTECTIVE
ORDER REGARDING PLAINTIFFS' SUBPOENAS DIRECTED TO
THIRD PARTIES**

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INTRODUCTION

Plaintiffs' brief in opposition to Defendants' Motion to Quash and for a Protective Order underscores the problems with their proposed third party subpoenas. First, Plaintiffs have not demonstrated that any Defendant has possession, custody, or control over documents in any foreign third party's possession, and thus no Defendant can be ordered to respond to any of the unserved foreign third party subpoenas. Second, all of the subpoenas are overbroad because they exceed the scope of the Macro Discovery Order, which is the law of the case. Plaintiffs cannot credibly maintain that they should be permitted to obtain discovery from non-parties that is broader than the discovery required of the parties. Third, Plaintiffs have conceded that they did not provide adequate notice of the subpoenas to Defendants because Plaintiffs ignored Defendants' requests for the document requests Plaintiffs proposed to include in the subpoenas. That Plaintiffs were required to serve subpoenas as known to all, what those subpoenas would be requests was required to be identified to Defendants.

For these reasons and others, as described more fully below and in Defendants' opening brief, Defendants respectfully request the Court to grant Defendants' Motion to Quash and for Protective Order.

FACTUAL BACKGROUND

Plaintiffs originally attempted to serve 75 subpoenas purportedly related to the 7 different manufacturer defendants. As set forth in Defendants' moving brief, and which has not been disputed by Plaintiffs, each of the subpoenas was virtually identical, seeking approximately 11 different categories of information, notwithstanding the very different businesses represented by each of the third parties.

Twenty-three of the subpoenas sought documents from foreign third parties. To the best of Defendants' knowledge, Plaintiffs have not effected foreign service on any of these subpoenas. Thus, none of the foreign third parties have responded and all twenty-three foreign subpoenas are at issue (the "At-Issue Foreign Subpoenas").

Despite Defendants' request for updated information regarding service of and responses by third parties, Plaintiffs have not provided Defendants with any additional information since Defendants filed their moving Brief. As such, at the time of this Reply, Plaintiffs have apparently served 49 domestic subpoenas¹, and have received written objections and responses from at least eight Third Parties and

¹ Based on the 49 affidavits of service provided to Defendants, it appears Plaintiffs have attempted service on several third parties more than once by way of different corporate recipients and registered agents. Accordingly, the number of Subpoenas served does not correspond to the number of third parties served.

documents from three Third Parties. *See* Dkt. 652-11; *see also* Dkt 652 at 8. Another five Third Parties informed Plaintiff that they have no responsive documents or information. *Id.* Thus, there are at least thirty-three domestic subpoenas at issue (the “At-Issue Domestic Subpoenas”). The number of third parties who have already objected to the subpoenas as well as those indicating that they have no responsive documents illustrates that many of the third parties who have been served take issue with the vast overbreadth of the subpoenas and the lack of relevance of Plaintiffs’ requests.

ARGUMENT²

I. DEFENDANTS ARE NOT REQUIRED TO RESPOND TO FOREIGN SUBPOENAS THAT HAVE NEVER BEEN SERVED ON THE THIRD-PARTIES.

² As a threshold matter, in their Opposition, Plaintiffs argue that Defendants lack standing to Quash or Modify the third party subpoenas because Defendants have not alleged any specific injury that would result from this subpoena process. *See* Dkt. 705 at 2-3. Plaintiffs assertion is incorrect as Defendants have repeatedly alleged with specificity that if Plaintiffs were permitted to engage in this overboard and indiscriminate subpoena process it would violate the Macro Discovery Order and the Law of the Case which would result not only in Plaintiffs’ circumvention of the established scope of discovery in this case but would also implicate widespread confidentiality and privacy concerns for Defendants. Defendants clearly have standing to challenge these subpoenas, as this Court has recognized that a party has standing to quash a subpoena to a third party if the subpoena seeks irrelevant information. *See Costantino v. City of Atl. City*, 2015 WL 12806490, at *3 (D.N.J. Nov. 4, 2015); *Cooper Health Sys. v. Virtua Health, Inc.*, No. CV 09-735(RMB/JS), 2009 WL 10727982, at *3 n. 2 (D.N.J. July 1, 2009) (Schneider, J.) (rejecting a standing argument where a party has standing “to object to subpoenas that were issued in contravention of a Court Order.”); *see also* Dkt. 652 at 9-10.

Having failed to effect foreign service of the At-Issue Foreign Subpoenas as required under Rule 45, Plaintiffs take the extraordinary step of asserting that Defendants should accept service of those subpoenas on behalf of the third parties and Defendants should collect and produce any responsive documents in those third parties' possession. Dkt. 705 at 5-8. However, Plaintiffs' cannot simply skirt their obligations under Rule 45.

First, the Court cannot compel Defendants to accept service of a subpoena served on a third party. Any such acceptance must be authorized by the third party. *See Laffey v. Plousis*, , 2008 WL 305289, at *5 (D.N.J. Feb. 1, 2008), *aff'd*, 364 F. App'x 791 (3d Cir. 2010) (holding service improper even though fellow employee at defendant's office said he was authorized to accept service, since apparent authority to accept service must be created by acts of the principal – not the agent); FED. R. CIV. P. 45(b)(1). Second, Plaintiffs cannot fill the void of foreign service of the At-Issue Foreign Subpoenas with the claim that Defendants have possession, custody or control over the third parties such that Defendants can simply collect and produce documents in the third parties' possession. A party is not obligated to produce documents that it does not possess or cannot obtain.³ *Princeton Digital*

³ Defendants note that, in Footnote 8 of their moving Brief in support of their Motion to Quash (Dkt. 652), they explained why it was improper for Plaintiffs to refuse to attempt service on the foreign third parties through the proper channels *i.e.* the Hague Convention protocols, and instead insist that Defendants must accept service of the Subpoenas directed to foreign third parties due to Defendants' alleged possession,

Image Corp. v. Konami Digital Entertainment Inc., 316 F.R.D. 89 (D. Del. 2016); *see also Eisenband v. Pine Belt Auto., Inc.*, 2020 WL 1486045, at *8 (D.N.J. Mar. 27, 2020) (awarding Defendant summary judgment because Plaintiffs could not show that Defendant had control over third party's documents). And Plaintiffs have not made any showing that any Defendant can obtain documents from any third party subject to an At-Issue Foreign Subpoena.

Plaintiffs make the general claim that “*many* technical quality agreements between Defendants and the third parties include provisions related to document retention policies, and the amount of time in which records will be made available to Defendants.” Dkt. 705 at 7. Defendants acknowledge that, in Footnote 6 of the Opposition, Plaintiffs cite and reference as exhibits four specific agreements between third parties and Defendants Torrent, Mylan, and Aurobindo, respectively. *Id.* at n.6.⁴ However, it is Plaintiffs’ obligation to cite specific language in governing

custody and control of the foreign third parties’ documents. However, because Plaintiffs again assert a similar argument in their Opposition and also demand that Defendants conduct the document collection and production on behalf of the foreign third parties, Defendants offer this response to Plaintiffs’ argument in the instant Reply.

⁴ Defendant ZHP notes that Plaintiffs failed to cite or provide any such technical quality agreement between ZHP and any of the third parties allegedly connected to ZHP. Therefore, Plaintiffs have failed to make a *prima facie* showing that ZHP has possession, custody or control over any foreign third parties’ documents based upon specific language in a governing agreement.

agreements between a particular third party and a particular Defendant in order to establish a Defendant's control over a third party's documents, not simply put forth a blanket statement that many Defendants and third parties have quality control agreements and then provide only a few examples of such. *See Eisenband*, 2020 WL 1486045, at *8; *Princeton Digital Image Corp.*, 316 F.R.D. at 90.

Significantly, the case law that Plaintiffs cite to argue that Defendants have an obligation to produce documents from the Third Parties in response to the Subpoenas does not concern subpoenas at all. *See* Dkt. 705 at 6-7. Rather, all of the cited authority concerns disputes over a party's production of documents in response to Rule 34 requests. *See e.g. Haskins v. Travelers Cas. & Sur. Co.*, 827 F. Supp. 2d 498 (W.D. Pa. 2011) (dispute regarding whether Rule 34(a) required defendant insurance company had control of its own agents' closing files); *Swindell Dressler Int'l Co. v. Travelers Cas. & Sur. Co.*, 827 F. Supp. 2d 498 (W.D. Pa. 2011) (decision regarding Rule 34 and spoliation concerning destruction of insurer's underwriting documents in coverage dispute with purported insured); *Afros S.P.A. v. Krauss-Maffei Corp.*, 113 F.R.D. 127 (D. Del. 1986) (plaintiff motion to compel defendant production of parent corporation's documents under Rule 34(a)); *Mercy Catholic Med. Ctr. v. Thompson*, 380 F.3d 142 (3d Cir. 2004) (Rule 34 analysis to determine whether medial enter provide documents to subcontractor and intermediary in dispute concerning Medical Intermediary Manual); *Boucher v. First Am. Title Ins.*

Co., No. C10-199RAJ, 2011 WL 5299497 (W.D. Wash. Nov. 4, 2011) (plaintiff motion to compel defendant insurance company's production of documents in possession of third party repository of mortgage documents under Rule 34); *Rosie D. v. Romney*, 256 F. Supp. 2d 115 (D. Mass. 2003) (plaintiff motion to compel defendant production under Rule 34).

Moreover, Plaintiffs have inappropriately raised this issue in the context of their response to the Defendants' Omnibus Motion to Quash. In effect, by asserting the Defendants have an obligation to gather documents from third parties in response to third party subpoenas, Plaintiffs request an expansion of Rule 34 discovery. Plaintiffs' Rule 34 requests were finalized and Court-ordered over a year ago. It is too late for Plaintiffs to re-write those requests now.

Having failed to provide the Court with any case law requiring a party to respond to a third party subpoena because service on the third party was not effected, and having failed to present any evidence that any Defendant has "possession, custody, or control" over any third party such that it can obtain documents responsive to the subpoena from the third party, the At-Issue Foreign Subpoenas should be quashed.

II. ALL OF THE SUBPOENAS ARE OVERBROAD AND SHOULD BE QUASHED OR MODIFIED.

Plaintiffs should not be permitted to obtain discovery from non-parties that is broader in scope than what the parties themselves are obligated to provide under the

Court's rulings governing the scope of discovery in this case. Even if a third party is willing to provide discovery that exceeds the bounds of the Macro Discovery Order, such discovery would be an improper expansion of the law of the case. At a minimum, Plaintiffs should be directed to modify the subpoenas to reflect the four corners of the Macro Discovery Order. In particular, the subpoenas should not seek information relating to non-valsartan drugs, valsartan not sold in the U.S. market, and testing information beyond that specified in the Macro Discovery Order, which is the law of the case. *See* Dkt. 303 at ¶ 8.

As emphasized in detail in Defendants' moving brief, Plaintiffs' refusal to sharpen their pencils and narrowly tailor the categories and topics of requests in their At-Issue Subpoenas has resulted in one-size-fits-all subpoenas that are blatantly overbroad. Third party subpoenas issued under Rule 45 are subject to the limitation of Rule 26, and parties are not permitted to subpoena irrelevant documents with impunity. *Costantino v. City of Atl. City*, 2015 WL 12806490, at *3 (D.N.J. Nov. 4, 2015) (citing *Wahoo Int'l, Inc. v. Phix Doctor, Inc.*, (BLM), 2014 WL 3573400, at *2 (S.D. Ca. July 18, 2014)). The At-Issue Subpoenas contain virtually identical document requests across-the-board notwithstanding the fact that they are directed at myriad of different types of entities, which requires the third parties to provide information that has nothing to do with any of the claims or defenses in this case and

thus plainly reach beyond requests for relevant information proportionate to the case.

See FED. R. CIV. P. 26.

III. ALL OF THE SUBPOENAS SHOULD BE QUASHED BECAUSE THEY VIOLATED THE NOTICE REQUIREMENT OF RULE 45

The notice requirement under Rule 45 is simple and straightforward: “[i]f the subpoena commands the production of documents, electronically stored information, or tangible things or the inspection of premises before trial, then before it is served on the person to whom it is directed, a notice and a copy of the subpoena must be served on each party.” FED. R. CIV. P. 45(a)(4). Plaintiffs did not serve copies of the subpoenas on Defendants before they initiated service and they have admitted that the subpoenas were “in the process of being served on the [non-]parties identified therein” at the time Plaintiffs first sent copies of the subpoenas to Defendants. *See* Dkt. 652-10. Prior to service of the subpoenas, Plaintiffs identified only a list of entities that Plaintiffs intended to subpoena, but they did not provide any copies of the proposed subpoenas despite the fact the Defendants expressly asked Plaintiffs to provide copies of the proposed subpoenas or a list of information requested. *See* Dkt 652-9.

This is an overt violation of the plain language notice requirement of Rule 45 that requires Plaintiffs to provide copies of the subpoenas to Defendants ***before they are served on the third parties***. It is not, as Plaintiffs claim in their Opposition, merely a product of the parties not yet exhausting the meet & confer process, but

rather a fundamental failure on Plaintiffs' part to satisfy the requirements of Rule 45. *See* Dkt. 702 at 4. Plaintiffs did not provide the required prior notice under Rule 45 and therefore all of the third party subpoenas should be quashed. *See, e.g. Fla. Media, Inc. v. World Publ'ns, LLC*, 236 F.R.D. 693, 695 (M.D. Fla. 2006) (finding subpoenas issued to 80 non-parties void and unenforceable where the plaintiff failed to give prior notice to the defendant); *Coleman-Hill v. Governor Mifflin Sch. Dist.*, 271 F.R.D. 549, 555-56 (E.D. Pa. 2010) 555-56 (admonishing plaintiff's counsel for failing to serve copies of non-party subpoenas before serving them on third parties").

IV. PLAINTIFFS' ASSERTION ABOUT A PUBLIC HEALTH CRISIS IS MISPLACED.

Plaintiffs' assertion that this litigation involves a "public health crisis" rings hollow. Plaintiffs' opposition attempts to muddy the standing issue with an argument about whether the information being sought in the subpoenas is "important to public health and safety." Dkt. 705 at 3-4. Contrary to Plaintiffs' suggestion, whether the information sought is "important to public health and safety" has no bearing on whether Defendants have standing to bring this motion. Tellingly, the two cases Plaintiffs cite in support of their "public health and safety" argument are inapposite: neither involves standing or third party subpoenas. At bottom, Plaintiffs have cited no case law to support their position that because the information being sought in the subpoenas is "important to public health and safety," Defendants do not have standing, and Defendants are not aware of any. Even assuming, *arguendo*, that

“public health and safety” was relevant here, Plaintiffs’ argument fails on the merits. As Plaintiffs note in their briefing, public safety is just one of multiple factors to consider in an analysis of whether information is confidential. Dkt. 705 at 3. Further, none of the cases Plaintiffs cite stand for the proposition that wide swaths of otherwise confidential documents must be produced to the public. On the contrary, the cases Plaintiffs rely on involved limited requests. *See Arnold v. Pennsylvania, Dept. of Transp.*, 477 F.3d 105, 108 (3d Cir. 2007) (third party newspaper granted access to specific, limited documents from litigation involving public officials); *In re Avandia Marketing, Sales Practices and Products Liability Litigation*, 924 F.3d 662, 671 (3d Cir. 2019) (request to publicly file certain documents used during summary judgment).

V. CERTAIN OF THE AT-ISSUE FOREIGN AND DOMESTIC SUBPOENAS SHOULD BE QUASHED FOR INDEPENDENT REASONS.

A. THE SUBPOENAS ASSOCIATED WITH ZHP SHOULD BE QUASHED.

Plaintiffs originally proposed serving subpoenas on 22 third parties purportedly related to ZHP. However, in their opposition brief Plaintiffs argue about only four of those third parties, Azbil Telstar Technologies; Chemo Group India; Linhai Huanan Chemical Co. Ltd.; and VXL Life Sciences. *See* Dkt. 705, ¶VI.A. Thus, as

to the other 17⁵ subpoenas purportedly related to ZHP, ZHP's motion to quash or modify should be granted because Plaintiffs have made no attempt to defend those subpoenas. *See, e.g., Livingstone v. Haddon Point Manager LLC*, 2020 WL 7137852, at *6 n. 1 (D.N.J. Dec. 7, 2020) (Kugler, J.) (ruling an argument is waived where it is not raised in an opposition brief).⁶

The subpoenas issued to Azbil Telstar Technologies; Chemo Group India; Linhai Huanan Chemical Co. Ltd.; and VXL Life Sciences should also be quashed. As set forth above, Plaintiffs have not made any showing that ZHP has been authorized to accept service of these subpoenas on behalf of any of these third parties, and Plaintiffs have not demonstrated that ZHP has "possession, custody, or control" of any information in their possession, such that ZHP can be ordered to respond to these

⁵ Plaintiffs originally served a subpoena on Frederick Ball, an attorney at Duane Morris LLP, however Plaintiffs and ZHP have since reached an agreement wherein Plaintiffs agreed to withdraw this subpoena in exchange for an affidavit from Mr. Ball detailing his extremely limited involvement. Thus, at the time of the filing of their moving brief, there were 21 'active' subpoenas purportedly related to ZHP.

⁶ Of these 17 third parties, Plaintiffs have agreed to withdraw four: CABB AG, Shiva Pharmachen Pvt., Tiefenbacher API + Ingredients, and Malvern Instruments. Dkt. 705 at n. 8. Of the remaining thirteen, six have provided their own responses and/or objections to the subpoena, one has produced documents, and two have responded that they do not have responsive documents. To the extent the Court rules that those subpoenas should not be quashed or modified due to such responses or objections, the subpoenas proposed to be served on the following third parties should nonetheless be quashed or modified because Plaintiffs did not make any argument about those subpoenas in their opposition brief: Dohmen Life Science Services, Eversana Life Science Services, and ProPharma Group, Inc.

At-Issue Subpoenas.⁷ *See Princeton Digital Image Corp.*, 316 F.R.D. at 90 (D. Del. 2016); *Eisenband*, 2020 WL 1486045, at *8 (D.N.J. Mar. 27, 2020).

B. THE SUBPOENAS ASSOCIATED WITH MYLAN SHOULD BE QUASHED.

Similarly to the ZHP-directed subpoenas, Plaintiffs directed a total of 10 third party subpoenas to Mylan, but only asserted arguments with regard to two of those entities – Lantech Pharmaceuticals Ltd. (“Lantech”) and Snehaa Solvents (“Snehaa”) – in their opposition brief. Thus, 8 of the 10 subpoenas purportedly related to Mylan should be quashed as Plaintiffs have offered no defense of these subpoenas. Further, the Lantech and Snehaa subpoenas should also be quashed because Plaintiffs’ passing reference to quality technical

⁷ ZHP has already produced 148,198 pages of documents from foreign, non-party Prinbury BioPharm (“Prinbury”), who is outside this Court’s jurisdiction, in response to Plaintiffs’ extensive Rule 34 Requests for Production Directed to the Manufacturing Defendants. *See* Dkt. 328. Any relevant discovery pursuant to the Subpoena directed to Prinbury would be duplicative and cumulative of the extensive discovery already produced from Prinbury’s records. Further, the decision to direct a subpoena to Prinbury highlights Plaintiffs’ intent for the Subpoenas – to obtain evidence outside the scope of the Court’s orders limiting the scope of discovery in this matter. *See* Dkt. 303. To the extent Prinbury possesses materials responsive to the Subpoena that have not already been produced in response to the Rule 34 Requests, which were heavily-litigated and limited in scope by the Court’s Macro Discovery Order (Dkt. 303), those materials are outside the scope of discovery ordered by the Court. *See Cooper Health*, 2009 WL 10727982, at *2 (D.N.J. July 1, 2009) (quashing subpoenas beyond scope of prior order limiting discovery).

agreements between Mylan and those entities does establish an obligation on the part of Mylan to obtain Rule 45 document discovery on behalf of Plaintiffs.

C. THE SUBPOENAS TO THE AUROBINDO RELATED THIRD PARTIES VIOLATE THE WORK PRODUCT DOCTRINE AND ATTORNEY CLIENT PRIVILEGE AND SHOULD BE QUASHED.

Aurobindo incorporates all arguments made in its Motion to Quash as to the subpoenas served on Meridian Consulting and ToxRox Consulting, LLC. The Subpoenas served on Meridian Consulting and ToxRox Consulting, LLC, must be quashed because they fall under the protection of the work product doctrine as both consulting firms were hired to assist counsel for Aurobindo in rendering legal advice in direct response to an FDA-Warning Letter. Alternatively, Aurobindo seeks entry of the proposed Protective Order (filed contemporaneously with Aurobindo's Motion to Quash (Dkt. 608-5) to allow its counsel to review the documents from both entities before they are produced to Plaintiffs' counsel. Alternatively, Aurobindo requests this Honorable Court Perform an in camera review of the documents to determine if the work product privilege applies.

In Plaintiffs' reply, they assert that "Defendants' documents make it obvious that these consultants were retained for the purpose of responding to an FDA 483 letter and not for the express purpose of preparing for litigation." Dkt. 705 at 13. Furthermore, Plaintiffs have stated that "Meridian was retained in 2019 to conduct

an independent assessment in response to the FDA's warning letter sent to Aurobindo." *Id.*

By Plaintiffs' own admission, Aurobindo retained Meridian and ToxRox to respond to an FDA Warning letter. This set of facts falls squarely within the decision rendered in *Todd v. STAAR Surgical Co.*, 2015 WL 13388227, at *1 (C.D. Cal. Aug. 21, 2015). In *Todd*, Defendant filed a Motion to Strike allegedly privileged information from Plaintiff's Amended Complaint, wherein Plaintiff alleged that Defendants made misleading statements regarding regulatory compliance of one of its facilities. *Id.* Prior to the litigation, the FDA conducted a routine visit to the facility at issue and issued a warning letter. *Id.* at *2. In response, STAAR hired a law firm to provide legal advice regarding its response, who in turn, hired private consulting firms for assistance. *Id.* at *3. The consulting firms then hired their own independent consultants. *Id.*

The Court indicated that all the information learned by the attorneys hired by STAAR to assist in responding to the FDA warning letter "was derived from activities carried out with the purpose of assisting [the attorneys in providing] legal advice to STAAR in its response to the Warning letter." *Id.* at *9. Furthermore, the Court noted that "this work was carried out in anticipation of future regulatory and legal proceedings." *Id.*

Here, much like in STAAR, Aurobindo received an FDA warning letter and hired private consultants to assist outside counsel in providing legal advice to Aurobindo regarding its response to the same. With regard to establishing that documents are protected by the work product doctrine, it is not necessary that there is impending litigation, just that ominous litigation is objectively reasonable. *See Miller v. J.B. Hunt Transp., Inc.*, 339 N.J. Super. 144, 148 (N.J. App. Div. 2001). In *Miller*, the Court noted, a document may “be found to have been prepared in anticipation of litigation even though litigation [has] not been commenced or even threatened when the document was prepared.” *Id.* Plaintiffs’ contention that “Aurobindo has not made an identifiable specific claim of impending litigation” is misguided, as this is not the standard set forth above. Dkt. 705 at 13. Rather, a document is still protected by the work product privilege if “[a] document is prepared at the direction of an attorney before litigation has commenced ... if its use for litigation was the dominant purpose of preparing the document and if the attorney’s belief that litigation would ensue was objectively reasonable” (emphasis added). *K.L. v. Evesham Tp. Bd. of Educ.*, 423 N.J. Super. 337, 354 (N.J. App. Div. 2011). Receiving an FDA warning letter, one can only assume that litigation and/or regulatory proceedings will soon follow.

The Subpoenas served on Meridian and ToxRox, must be also quashed because they fall under the protection of the attorney-client doctrine as both

consulting firms were hired to assist counsel for Aurobindo in rendering legal advice in direct response to an FDA-Warning Letter. Alternatively, Aurobindo seeks entry of the proposed Protective Order (filed contemporaneously with Aurobindo's Motion to Quash, Dkt. 608-5) to allow its counsel to review the documents from both entities before they are produced to Plaintiffs' counsel. Alternatively, Aurobindo requests this Honorable Court perform an in camera review of the documents to determine if the attorney-client privilege applies.

In their response, Plaintiffs' have mischaracterized the standard for the application of the attorney-client privilege. Plaintiffs' argue that communications between an attorney and a third party, not the client, do not fall under the protections of the attorney client privilege. See Plaintiffs' Response to Defendants' Motion to Quash, p. 20. This contention wholly ignores the fact that "disclosures made to a third party consultant do not constitute a waiver when the disclosure is 'necessary for the client to obtain informed legal advice' or if the disclosure is made "to an 'agent' assisting the attorney in giving advice to the client.'" *In re Niaspan Antitrust Litig.*, 2017 WL 3668907, at *2 (E.D. Pa. August 24, 2017) (quoting *Westinghouse Elec. Corp. v. Republic of Phil.*, 951 F.2d 1414, 1423-24 (3d Cir. 1991).

In fact, ample case law suggests that communications by consultants hired by counsel to assist in rendering legal advice are protected by the attorney-client privilege. See *In re Niaspan Antitrust Litig.*, 2017 WL 3668907, at *2 (stating that

information shared with outside counsel for the purpose of providing legal advice is protected by the attorney-client privilege). Furthermore, the D.C. circuit has applied the attorney-client privilege to documents provided to outside consultants as the consultants were hired “to provide input to the legal department and or/receive legal advice and strategies formulated by counsel.” *See Federal Trade Commission v. GlaxoSmithkline*, 294 F.3d 141, 147 (D.C. Cir. 2002). Additionally, the attorney-client privilege was extended to third party consultants involved in rendering legal advice. *See In re CV Therapeutics, Inc. Sec. Litig.*, 2006 WL 1699536, at *7 (N.D. Cal. June 16, 2006).

These cases demonstrate that consultants hired to assist counsel in rendering legal advice to a client, fall under the protections of the attorney-client privilege. This is completely contrary to Plaintiffs’ contention that disclosures made to third parties waives the privilege. Dkt. 705 at 20. Here, Meridian and ToxRox were hired, as consultants, to assist outside counsel in rendering legal advice to Aurobindo in preparing its response to an FDA Warning letter. This type of relationship is contemplated in the above-referenced case law, and it has been held these communications are protected by the attorney-client privilege. *See United States ex rel. Strom v. Scios, Inc.*, 2011 WL 4831193, at *2 (N.D. Cal. October 12, 2011) (stating that “an independent consultant can be a representative of the client for purposes of applying the attorney-client privilege”) (quoting *In re Bieter Co.*, 16

F.3d 929 (8th Cir. 1994); *see also Serrano v. Chesapeake Appalachia, LLC*, 298 F.R.D. 271, 282 (W.D. Pa. March 6, 2014) (indicating that the client may permit disclosure to an ‘agent’ providing the attorney assistance in rendering legal advice to the client without waiving the attorney-client privilege.)

As stated, the documents in Meridian’s and ToxRox’s possession fall under the protections of the work product doctrine because Aurobindo’s outside counsel retained these firms in assistance with responding to an FDA Warning letter. A reasonable assumption, after receiving such a letter, is that litigation and/or regulatory proceedings will soon follow. This type of relationship, i.e., the consultant-attorney relationship, has routinely been protected by the work-product doctrine. Similarly, the documents possessed by the consulting firms fall under the protections of the attorney-client privilege. Not only have courts extended this privilege to the attorney-consultant relationship, this is true in the context when the consultants were hired to render legal advice. In this case, Aurobindo retained these firms specifically for legal advice in response to an FDA warning letter.

Accordingly, Aurobindo requests the subpoenas served on Meridian and ToxRox be quashed. Alternatively, Aurobindo requests entry of the proposed Protective Order to allow its counsel to review the documents and, if necessary, produce a privilege log and documents not protected by either the attorney-client or work product privilege. Alternatively, Aurobindo requests this Honorable Court

perform an in camera review of the documents to determine whether either of the privileges apply.

CONCLUSION

Therefore, for the foregoing reasons and those asserted in their opening brief in Support of their Motion to Quash or for a Protective Order, Defendants respectfully request the Court grant said motion.

Respectfully submitted,

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